

TECHNICAL DATA SHEET

1861-TDS-ENG-2025

UREA CRISTAL (EUR. PH.)			
DESCRIPTION DCI:		DESCRIPTION DOE:	
CAS Nº: 57-13-6	EC Nº: 200-315-5		AEMPS CODE:
MOL. WEIGHT: 60,1	MOL. FORMULA: CH4N2O		ARTICLE CODE: 1861

ATTRIBUTES	SHOULD BE White or almost white crystalline powder or transparent crystals, slightly hygroscopic Very soluble in water, soluble in ethanol (96 %), practically insoluble in methylene chloride		
Appearance			
Solubility			
Melting point	132 - 135 °C		
Identification A	Complies		
Identification B	Complies		
Appearance of solution	Clear and colourless		
Alcalinity	Complies		
Biuret	=< 0.1 %		
Ammonium	=< 500 ppm		
Loss on drying	=< 1.0 %		
Sulfated ash	=< 0.1 %		
Assay	98.5 - 101.5 %		
COMPLIES WITH			

European Pharmacopoeia 11.0

STORAGE

Store in a tightly closed container and in a dry place.

REMARKS

Urea is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.